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In the Supreme Court of the United States

OCTOBER TERM, 1978

Nos. 78-911 & 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,
v.
AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

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BRIEF FOR RESPONDENTS THE RUBBER MANUFACTURERS ASSOCIATION, INC., *et al.*

(Relating To The Dermal Contact Issue)

Of Counsel:

CLEARY, GOTTLIEB, STEEN
& HAMILTON
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036

July 30, 1979

CHARLES F. LETTOW
JOHN C. MURPHY, JR.
1250 Connecticut Ave., N.W.
Washington, D.C. 20036

Attorneys for
The Rubber Manufacturers
Association, Inc., *et al.*

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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(Relating To The Dermal Contact Issue)

QUESTION PRESENTED

The Occupational Safety and Health Administration ("OSHA"), petitioner in No. 78-1036, has presented two questions stemming from the decision of the court of appeals setting aside the airborne exposure provisions and the dermal contact sections of OSHA's benzene standard.[1] This brief addresses only the second of those questions, relating to the dermal contact sections of the benzene standard.[2] OSHA has posed the second question as a hypothetical inquiry divorced from the facts of this case. Restated to reflect the decision of the court below, that question is:

> Whether OSHA, in promulgating as part of the benzene standard a ban on dermal contact with liquids containing even small or trace amounts of benzene, was entitled to rely solely on outdated and inconclusive data while failing to obtain readily available evidence from "research, demonstrations, [and] experiments", as required by Section 6(b)(5) of the Occupational Safety and Health Act of 1970.

STATEMENT OF THE CASE[3]

A. Introduction

This case presents questions concerning two separate and essentially unrelated provisions of OSHA's Permanent Standard for Occupational Exposure to Benzene (the "benzene standard"). The first of these provisions regulates airborne exposure to benzene and requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of 1 part benzene per million parts of air (1 ppm) as an 8-hour time-weighted average. The second of the provisions operates independently of the airborne exposure limit and bans dermal contact with benzene or substances containing even small amounts of benzene.[4] (29 C.F.R. § 1910.1028(c)(2), Pet. App. 36a.)

Respondents the Rubber Manufacturers Association and six individual rubber companies (collectively "rubber companies")[5] are affected primarily by the second of the two major provisions of the benzene standard—the ban on dermal contact. Rubber companies manufacture tires, tennis balls, and a range of other products[6] from natural and synthetic rubber. In doing so, they use petroleum

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[1] The question presented by the Industrial Union Department, AFL-CIO ("IUD"), petitioner in No. 78-911, is essentially the same as the first question presented in No. 78-1036.

[2] The Brief for Respondents American Petroleum Institute, *et al.* (the "API Brief"), deals with the decision of the court below setting aside OSHA's permissible airborne exposure limit for benzene. Respondents The Rubber Manufacturers Association, *et al.* support the statement of issues and legal conclusions set out in that Brief. In turn, the respondents filing that Brief support the statements and arguments presented here. *See* API Brief, at 2 n. 2.

[3] Several abbreviations are used in this brief. "Pet. App." refers to the separately bound Appendix to the petition in No. 78-911. "A." refers to the Joint Appendix filed in these cases. The complete record of OSHA's proceedings on the original benzene standard and the June 1978 amendment to the standard is on file with this Court. References to the record of the original standard are as follows: Transcript—"Tr."; Exhibit—"Ex." References to the record of the amendment to the benzene standard are: Transcript—"Amend. Tr."; Exhibit—"Amend. Ex."

[4] A related provision of the standard requires employees to wear protective clothing and equipment where dermal or eye contact may occur. 29 C.F.R. § 1910.1028(h), Pet. App. 42a. The sections of the standard banning dermal contact (29 C.F.R. § 1910.1028(c)(2)) and requiring the use of protective clothing and equipment (29 C.F.R. § 1910.1028(h)) are referred to collectively as the "dermal contact sections" or the "dermal contact provisions".

[5] The six companies are The Armstrong Rubber Company, The Firestone Tire & Rubber Company, The General Tire & Rubber Company, The B. F. Goodrich Company, The Goodyear Tire & Rubber Company, and Uniroyal, Inc.

[6] These other products include such diverse items as inner tubes, hoses, v-belts, conveyor belts, adhesives, cements, tennis shoes, shoe products, and health and hospital products. *E.g.*, Amend. Ex. 46-59, at 1.

solvents, cements and other materials which contain benzene in small or trace amounts (less than 1.0 percent) as an unintentional ingredient. These solvents, cements and other materials are used as tackifying agents to enhance adhesion of various components of rubber company products (such as tire plies or tennis ball covers) during the manufacturing process. During the manufacture of such rubber products, there is necessary periodic skin contact with these tackifying agents.

The fact that skin contact with solvents containing small amounts of benzene cannot be avoided in rubber company manufacturing operations is not in dispute. Indeed, OSHA conceded to the court below that the rubber companies had "advanced a real problem" in contesting the feasibility of compliance with the dermal contact sections.[7] And in announcing the amendment to the benzene standard, OSHA admitted that:

> *[I]n tire-building, the record evidence shows that at present there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene.* (A. 266 (emphasis added).)

Especially in view of the record and OSHA's own prior statements, rubber companies were surprised by, and strongly disagree with, OSHA's characterization of the second issue in this case as involving simply a "protective clothing requirement". (OSHA's Brief at 4, 13, 39, 74; *compare id.* at 15, 25, 35, 82 ("dermal prohibition").) The dermal contact provisions operate to ban skin contact with liquids containing even small amounts of benzene.[8] Where it is not possible to use protective clothing and equipment—as is the case with rubber manufacturing operations—the dermal provisions among other things would effectively bring "domestic tire production to a virtual standstill."[9] It is for that reason that rubber companies sought review of OSHA's decision to ban dermal contact with liquids containing small amounts of benzene, without a proper scientific or factual basis for doing so.

[7] A. 231, Amend. Ex. 32-A-3 (OSHA's Supplemental Memorandum in Opposition to Stay, Apr. 11, 1978) at 67. There is no factual basis whatsoever for the assertion in OSHA's Brief that "[i]t is unquestioned that the use of protective clothing to prevent dermal or eye contact with benzene-bearing liquids is feasible". OSHA's Brief at 81 n. 64. Given the uniform record evidence to the contrary, including OSHA's own prior statements, this assertion in OSHA's Brief is inexplicable.

Indeed, the infeasibility for rubber companies of compliance with the dermal contact sections was a principal issue raised before the court of appeals. As discussed *infra*, at 16, the court of appeals did not reach that issue.

B. The Original Benzene Standard

OSHA's Brief describes in part the record of the original benzene proceeding respecting the dermal contact sections. (OSHA's Brief at 25-28.) While rubber companies do not believe that OSHA's statement fully sets forth the record evidence in that regard, that evidence is summarized in rubber companies' Joint Memorandum in Opposition to the petitions for certiorari (at 8-12). In the interest of brevity, this truncated counterstatement of the case begins with the issuance of the benzene standard by OSHA on February 3, 1978.

In contrast both to OSHA's emergency temporary standard ("ETS") for benzene and to its proposed benzene standard, each of which contained exclusions for

[8] As described *infra*, at 9-13, OSHA has varied the extent of the ban on dermal contact since the issuance of the benzene standard. The standard as originally adopted by OSHA prohibited all dermal contact with any liquid containing any amount of benzene. In the first five months following adoption of the standard, OSHA twice modified the extent of the ban on dermal contact. However, the court of appeals stayed the entire benzene standard before its effective date, and the standard has never gone into effect.

[9] A. 207, Amend. Ex. 32-F-2 at 22.

mixtures containing small amounts of benzene,[10] OSHA's permanent standard provided no such exclusion. The permanent standard banned all dermal contact with liquid mixtures containing any amount of benzene (29 C.F.R. § 1910.1028(c)(2), Pet. App. 36a), and required employees to wear protective clothing and equipment where dermal exposure might occur (29 C.F.R. § 1910.1028(h), Pet. App. 42a). It also required employers to affix "Cancer Hazard" labels on *all* containers of *all* products containing *any* amount of benzene. (29 C.F.R. § 1910.1028(k), Pet. App. 47a-48a.)[11]

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[10] The ETS exempted from its coverage mixtures containing 1.0 percent benzene or less. 42 *Fed. Reg.* 22515, 22525 (May 3, 1977), Ex. 1. Respecting dermal contact, the effect of that exemption was to permit employees to have dermal contact with mixtures containing 1.0 percent benzene or less. Because rubber company manufacturing operations use liquids containing less than 1.0 percent benzene, those operations were not affected by the dermal contact sections of the ETS. The proposed standard, like the ETS, contained a volume percentage exclusion, exempting from the standard's coverage work operations where "the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of this standard) or less of benzene by volume, or the vapors released from these liquids." 42 *Fed. Reg.* 27451, 27460 (May 27, 1977), Ex. 4.

[11] Because benzene is present in minute quantities in water supplies throughout the country, as well as in everyday foods and elsewhere throughout our society, as initially promulgated OSHA's standard would have produced absurd results. It would have imposed a ban on drinking water in workplaces in the United States and would have required that all workplace drinking fountains bear a "readily visible and legible" label stating: "CAUTION—CONTAINS BENZENE—CANCER HAZARD". 29 C.F.R. § 1910.1028(b), (c)(2), and (k)(2)-(4), Pet. App. 36a, 42a, 47a-48a. *See* the opinion of the court of appeals, Pet. App. 12a, 581 F.2d at 500. For the same reason, employees would have been barred from washing their hands or taking showers at workplaces. Solid materials would also have been affected. For example, the same label would have been required to be affixed to all cans of tennis balls made in the United States, but not to cans of tennis balls manufactured abroad.

In announcing the permanent standard, OSHA offered no explanation for its last-minute and unexpected elimination of the exclusion for liquid mixtures with small amounts of benzene. OSHA did not even mention that removal of the exclusion had the effect of drastically changing the scope and impact of the dermal contact provisions in particular. The Agency imposed the draconian prohibition against dermal contact even though in the preamble announcing the permanent standard, it acknowledged that "[i]nhalation is the primary route of entry of benzene in man." (Pet. App. 78a.) OSHA made its decision on the basis of its "policy" (Pet. App. 192a), while conceding that it did not know whether benzene is absorbed through intact skin:

> The record evidence on the effect of liquid benzene on the eyes or the skin is *extremely limited.* No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans are *not definitive* as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin. (Pet. App. 193a (citations omitted) (emphasis added).)

Consistent with this lack of knowledge, the medical surveillance guidelines for benzene contained in an appendix to the standard stated that "[b]enzene is primarily an inhalation hazard" and that "*[t]he extent of absorption through the skin is unknown.*" (Pet. App. 58a (emphasis added).)

Rubber companies filed a request with OSHA for a stay of the dermal contact provisions and certain other sections of the standard. That request focused particularly on the fact that it was not feasible for rubber companies to continue their manufacturing operations in compliance with the ban on dermal contact. Manufacturing operations for tires, tennis balls, v-belts, conveyer belts, hose and other products necessarily involve dermal

contact with solvents containing small amounts of benzene (less than 1.0 percent.)[12]

The manufacture of tires, for example, involves the use of petroleum-based solvents as tackifying agents essential to the tire building process. (A. 190-191, 206-207, 210-212, 217-219, 225; Amend. Tr. 87-89, 160-167, 185-186.) Layers of materials ("plies") swabbed with solvent are manually built up to construct tires. (*Id.*) To achieve the precision of attachment and adhesion critical for tire uniformity and compliance with government tire safety standards, full use and dexterity of the workers' hands is required. (*Id.*) Skin-tight gloves impervious to most liquids cannot be used; they would dissolve or become tacky upon contact with petroleum solvents and actually lead to greater hazards and exposure. (A. 191, 207, 212, 219, 225, 228.)

In tire building and other rubber company operations, there are no suitable substitutes for petroleum solvents which contain small amounts of benzene as a contaminant. (A. 199, 218; Amend. Tr. 115-116.) Despite repeated requests by rubber companies, it is not possible to obtain from suppliers solvents which do not contain trace amounts of benzene. (A. 207, 212, 218, 225, 228; Amend. Tr. 87, 153, 168, 186-187, 208-209, 213.) While the benzene content of such solvents has declined in recent years, it remains typically above 0.1 percent and in some instances exceeds 0.7-0.8 percent. (A. 199, 225, 228; Amend. Tr. 131, 151-153, 175-178, 196-197.) Very substantial quantities of solvents, exceeding 110 million gallons annually, are purchased by rubber companies throughout the United States from a number of suppliers. Moreover, the benzene content of solvents varies among

[12] *E.g.*, Request for Stay on Behalf of Rubber Companies (Mar. 3, 1978), Amend. Exs. 27-E.1 and E.2; Amend. Ex. 46-59, at 3-9; A. 206, 211, 212, 217, 222-223, 228; Amend. Tr. 78-82, 87-89, 132-133, 160-167, 212.

suppliers, among different plants of the same supplier, and even among different shipments from the same plant of the same supplier. (Amend. Tr. 117-118, 175-178, 200-201, 207-209.)

In response to the various requests for stay, on March 8, 1978 OSHA informed rubber companies and other industry respondents that it was "going to stay the standard as it applie[d] to work operations where the sole exposure to benzene is from mixtures containing 0.1 percent or less benzene." (A. 204.)

C. The Amendment To The Standard

Thereafter on March 28, 1978, OSHA published a notice of its limited stay of the standard[13] and of a rulemaking proceeding to amend the standard. (43 Fed. Reg. 12890-12891, Amend. Ex. 4.)[14] That notice proposed an amendment to exclude from the standard l quid mixtures containing 0.1 percent or less of benzene. The announcement sought to limit the points at issue in the new administrative proceedings to nine specific questions, and interested persons were instructed to address the proposed percentage exclusion only as it related to "airborne concentrations" of benzene. (*Id.* at 12891.) Notwithstanding OSHA's lack of evidence as to whether dermal contact with liquid mixtures containing small amounts of benzene constituted a health hazard, OSHA sought no evidence on that issue. Moreover, in the administrative proceedings OSHA refused to consider such evidence even

[13] OSHA's stay had no legal effect. The entire benzene standard had previously been stayed by the court of appeals.

[14] OSHA further modified the scope of the standard by means of a "correction" document published March 31, 1978. 43 *Fed. Reg.* 13561-13563, Amend. Ex. 3B. Among other changes, OSHA "corrected" the preamble to the standard so as to exclude from the standard solids containing benzene (other than pure solid benzene, which generally exists only in scientific laboratories). One effect of this "correction" was to exclude cans of tennis balls and boxes of tennis shoes from the requirement that they be labeled as a "CANCER HAZARD". *See supra*, at 6 n. 11.

after the rubber companies expressly warranted to the Agency that Dr. Howard Maibach[15] was conducting a study of issues relating to dermal exposure to benzene.

During the new rulemaking proceeding, the rubber companies informed OSHA explicitly that Dr. Maibach had been commissioned to conduct a skin absorption test. (Amend. Tr. 71.) Dr. Maibach's own description of his testing program was received into evidence at the hearing on the proposed amendment to the standard. (Amend. Tr. 71-73.)[16] Nevertheless, Grover Wrenn, OSHA's Director of Health Standards Programs, flatly stated at the hearing that OSHA would not await the results of such a study even though these results could be made available to it within 180 days. (A. 185.)[17] Mr. Wrenn further testified that OSHA did not have any independent plans to obtain data to determine whether a hazard existed from dermal exposure to mixtures containing small amounts of benzene. (A. 183-184.)

Rubber companies participated extensively in the new rulemaking and presented detailed evidence on the infeasibility of complying with the dermal contact sections as proposed in the amendment. (*E.g.*, A. 187-201, 205-229, 232-238; Amend. Ex. 46-41, 46-58, 46-59, 46-80, 74, 75, 78.) Among other things, rubber companies strongly urged OSHA to provide in the standard for at least a parity of requirements for airborne and dermal exposure.

[15] Professor of Dermatology, University of California Medical Center.

[16] Dr. Maibach was unable to appear in person because of his teaching schedule.

[17] The question to Mr. Wrenn was based on a 180-day period because such a period had been specified in a pending proposal by OSHA for a standard relating generically to substances posing a potential carcinogenic risk. *See infra* at 42 n. 78.

Dr. Maibach has now in fact completed his study of the absorption of benzene in which he performed straightforward and reliable tests using radioactive-tagged benzene with rhesus monkeys. *See infra*, at 35-36 n. 69.

The companies advocated adoption of a special "dermal action level" that would permit dermal contact with liquids containing small amounts of benzene, similar in concept to the "action level" already in the standard for airborne exposure to benzene.[18] (Amend. Ex. 46-59, at 1-3; A. 190, 192, 213, 235-237; Amend. Tr. 67-68, 76, 95, 98-99, 136-137, 159, 170, 188-191, 212-215.) Such a dermal action level would provide an exemption only for dermal contact with liquids containing small amounts of benzene.[19]

In support of the proposed dermal action level, The B. F. Goodrich Company presented the results of experimental work and calculations performed to determine the relationship between entry of benzene into man through inhalation of airborne benzene and possible skin absorption of benzene contained in rubber solvent. Based on the existing literature, Goodrich concluded that the maximum absolute benzene absorption from a tire builder's use of rubber solvent containing 1.0 percent benzene (which is higher than the 0.5 percent or less benzene normally contained in such solvents) was only one-third of the permitted airborne benzene exposure at the 1 ppm permissible exposure limit of the benzene standard. (A. 193-197, 234-238.)[20] Even though an OSHA representative

[18] An employer is exempt from many of the requirements of the standard if airborne concentrations do not exceed the "action level" of 0.5 ppm. *See* 29 C.F.R. § 1910.1028(b), (e)(3), Pet. App. 35a, 37a-38a.

[19] Where solvents were used with a benzene content greater than the across-the-board percentage-exclusion level then proposed by OSHA, but less than the dermal action level, the user of the solvent would have been required to comply with the airborne exposure provision.

[20] The Goodrich calculations were based on skin absorption data contained in the only study in the record showing *any* absorption of benzene through the skin (using 100% benzene, rather than solvent containing benzene). A. 107-120. The authors of that study described their results as reflecting the "extreme case" (A. 117) and OSHA itself has described the study as not "definitive". OSHA's Brief at 27 n. 29.

[Footnote continued on page 12]

stated at the hearing that Goodrich's experiment was "fascinating" and that "if it were true, it could have some effect on [the suggested] dermal action level" (A. 194), the suggested dermal action level was ignored by OSHA (*e.g.*, Amend. Tr. 62-63) and OSHA did not even advert to the Goodrich information in announcing the amendments to the benzene standard. OSHA adopted a percentage exclusion amendment without revising in any other way the harsh dermal contact provisions of the standard.

OSHA announced the amendments to its benzene standard in late afternoon on the day before oral argument in the court of appeals.[21] (Pet. App. 2a n.4, 581 F.2d at 496 n.4.) For three years OSHA exempted liquid mixtures containing 0.5 percent or less benzene from the provisions of the standard, and thereafter mixtures containing 0.1 percent or less benzene.[22] In doing so, OSHA

[20] [Continued]

Skin absorption data from Dr. Maibach's studies show that the study used by Goodrich led Goodrich to substantially *overestimate* skin absorption of benzene. Dr. Howard Johnson recently completed a comparative study of the human systemic exposure to benzene resulting from dermal and inhalation exposure, using Dr. Maibach's skin absorption data. Dr. Johnson's study was furnished to OSHA on July 24, 1979 and a copy has been lodged with the Clerk of this Court. Dr. Johnson compared conditions of dermal exposure in passenger tire manufacturing operations using solvent containing 0.35 percent benzene with conditions of inhalation exposure to air with 1 ppm benzene. He concluded that maximum pulmonary absorption of benzene would be 15 times greater than maximum dermal absorption. Dr. Johnson's report further found that at OSHA's currently-effective 10 ppm limit of benzene in air, maximum pulmonary absorption of benzene would be 150 times greater than maximum dermal absorption.

[21] The court of appeals and the private litigants learned of the amendments that afternoon during a pre-argument conference held in the chambers of one of the circuit judges assigned to the panel of the Fifth Circuit hearing the case.

[22] OSHA also exempted certain previously-packaged mixtures from the standard's labeling provisions.

recognized that "in tire-building . . . there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene." (A. 266.) OSHA nonetheless chose not to modify the dermal contact provisions, but rather to rely on the across-the-board percentage exclusion to provide a modicum of temporary relief for three years.[23] For the longer term, OSHA speculated as to the possibility of increased production of solvents containing less than 0.1 percent benzene and other unspecified technological developments (A. 266), without citing any factual basis for its speculation and in the face of substantial evidence to the contrary. OSHA cited no new health evidence in support of the amendment.

D. The Decision Of The Court Of Appeals

On October 5, 1978, the court of appeals issued its decision granting the petitions for review of the benzene standard, setting aside the airborne permissible exposure limit and the dermal contact provisions, and also vacating the remaining provisions of the standard.

Specifically, the court of appeals vacated the dermal contact provisions on two separate and alternative grounds.[24] The court noted at the outset that OSHA's prohibition against dermal contact was based on " 'OSHA's *policy* that, in dealing with a carcinogen, all potential routes of exposure (*i.e.*, inhalation, ingestion, and skin absorption) be limited to the extent feasible.' "

[23] Rubber companies can in most cases obtain solvents at or less than the 0.5 percent level for use in their Eastern, Southern and Midwestern tire and other manufacturing plants. Even for these plants, the companies often are close to or at the 0.5 percent level without any margin for deviation. A. 189-190; Amend. Tr. 117, 166-168. For West Coast plants, however, the 0.5 percent level could not be met, since in some instances suppliers could only meet a limit of 0.7 percent benzene in suitable solvents. Amend. Tr. 168, 176. These differences in solvents stem from available crude oil supplies. *Id.* at 168.

[24] The court did not reach the issue of feasibility of the dermal contact provisions, the third asserted ground for setting the provisions aside. *See infra*, at 16.

(Pet. App. 22a (quoting 43 Fed. Reg. 5948, Pet. App. 192a), 581 F.2d at 505 (emphasis added).) Rejecting OSHA's claim that its decision to prohibit dermal contact with liquid mixtures containing small amounts of benzene was supported by "substantial evidence",[25] the court stated that:

> OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional research could be attempted, but might not shed new light on a subject. (Pet. App. 26a-27a, 581 F.2d at 507.)

[25] OSHA incorrectly asserts that the court of appeals found OSHA's adoption of the dermal contact sections to be supported by "substantial evidence". OSHA's Brief at 74. To the contrary, the court, after reviewing the "dated, inconclusive data" relied upon by OSHA, stated that "OSHA's finding that dermal contact with benzene poses a cancer risk *could* pass muster" if that had been the only evidence in the record. Pet. App. 25a, 581 F.2d at 507 (emphasis added). The court then considered Dr. Maibach's testimony describing available and reliable experimental techniques which could resolve within a relatively short term the issue of whether human skin absorbs benzene, and found that Dr. Maibach's "additional evidence remove[d] the support for OSHA's actions." *Id.*

Indeed, at a prior point in its opinion, where the court summed up its ruling on the dermal contact provisions, the court stated:

> The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene . . . [is reasonably necessary]. Pet. App. 23a-24a, 581 F.2d at 506.

Moreover, a finding like that which the government suggests was made would have required the court of appeals to reach the feasibility issue, which the court specifically reserved.

In reaching that conclusion, the court reviewed in detail the record evidence on the issue of skin absorption of benzene. That review encompassed not only the "dated, inclusive" data, but also Dr. Maibach's "unrefuted testimony" as to "simple experimental techniques" that were reliable and accurate and that could provide "readily available" factual information relating to benzene absorption. On the basis of that detailed factual review, the court held that:

> OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption of benzene through the skin which might cause cancer is in clear disregard of the congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record. (Pet. App. 27a, 581 F.2d at 508.)

The court of appeals also vacated the dermal contact provision on the ground that it was not "reasonably necessary" as required by Section 3(8) of the Occupational Safety and Health Act of 1970 (the "Act"), 29 U.S.C. § 652(8). OSHA had sought in the court of appeals to justify the dermal contact prohibition as an adjunct to the permissible airborne exposure limit and on the basis of a concern for dermatitis. Both contentions were rejected. The court's analysis of the record led it to conclude that the argument of dermatitis "appear[ed] to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to [that] provision." (Pet. App. 22a, 581 F.2d at 505.) Because review of the standard "must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it" (Pet. App. 23a, 581 F.2d at 506),[26] the court refused to

[26] As authority for this principle, the court cited *Dry Color Mfrs.' Ass'n* v. *Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973), which in turn cites and relies on this Court's decisions in

give weight to the newly proffered argument on dermatitis. And noting that the record did not support OSHA's finding that benzene is absorbed through the skin, the court determined that:

> [T]he record will not support a finding that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too. (Pet. App. 23a-24a, 581 F.2d at 506.)

Rubber companies had raised the infeasibility of the dermal contact provisions as a third ground for setting the provisions aside. However, the court of appeals did not reach the issue of whether OSHA's ban on dermal contact was "feasible" within the meaning of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), stating that the amendment to the standard on June 21, 1978, "significantly affect[ed] the feasibility issue . . . ." (Pet. App. 23a, 581 F.2d at 506.)[27] As the court set aside the dermal contact provisions on the two other grounds, it could decide the case without ruling on the feasibility issue.[28]

Citizens to Preserve Overton Park v. *Volpe*, 401 U.S. 402, 419 (1971), *National Labor Relations Board* v. *Metropolitan Life Ins. Co.*, 380 U.S. 438, 443-444 (1965), and *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 168-169 (1962), along with *United States* v. *Allegheny-Ludlum Steel*, 406 U.S. 742, 756-757 (1972).

[27] Because the amendment to the standard had been issued literally on the eve of oral argument, at the close of the argument the court of appeals had ordered the parties to file supplemental briefs on an expedited basis directed to the effect of OSHA's amendment on the litigation.

[28] *See* OSHA's Brief at 31 n. 32. OSHA is simply wrong when, at a subsequent point in its brief, it asserts that the feasibility of the dermal contact provisions was and is "unquestioned". *Id.*, at 81 n. 64. *See supra*, at 4 n. 7.

SUMMARY OF ARGUMENT

The court of appeals correctly decided that OSHA's decision to ban dermal contact with liquids containing even small or trace amounts of benzene was not supported by "substantial evidence", as required by Section 6(f) of the Act, 29 U.S.C. § 655(f), and was not "reasonably necessary" to protect workers' health, within the meaning of Section 3(8) of the Act, 29 U.S.C. § 652(8).

Whether there is substantial evidence supporting OSHA's ban on dermal contact must be determined with reference to the standard-setting criteria in Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5). Those criteria reflect a clear Congressional mandate that OSHA standards be properly premised on a factual, scientific basis. Section 6(b)(5) directs that OSHA standards for toxic materials or harmful physical agents "*shall be based upon research, demonstrations, experiments, and such other information as may be appropriate*" (emphasis added), and requires that OSHA shall consider "the latest available scientific data in the field . . . ." These specific evidentiary criteria were added to Section 6(b)(5) in the Senate, after an earlier, more general House Committee version of that section was criticized as allowing standards to be based on " 'views and arguments' rather than probative evidence." (*See infra*, at 28.)

The legislative history of the Act is directly contrary to OSHA's assertion that it has unfettered discretion to determine whether it is appropriate to obtain factual information to support particular provisions of its standards. By requiring that OSHA act from "research, demonstrations, [and] experiments", Congress expressed its intent that OSHA standards be scientifically-based and factually supported. The emphasis on the need for scientific research in standard-setting meshes with the "research" provisions of the Act, which give OSHA the

means to obtain necessary factual information by contracting directly for scientific research or other studies (Section 20(c)) and which created a new National Institute of Occupational Safety and Health to conduct "research, experiments, and demonstrations relating to occupational safety and health" (Section 20(a)(1); *see* Sections 20(e), 22).

In the face of the specific mandate of Section 6(b)(5), OSHA has shown an evident lack of concern for addressing the question of skin absorption of benzene. OSHA's own statement of its reasons for the ban on dermal contact is startling for its lack of any significant scientific or factual basis. OSHA seeks to justify the dermal contact prohibition based on the Agency's "policy", while admitting that the record evidence is "extremely limited" and the "few studies" are "not definitive" (Pet. App. 192a-193a), and at the same time acknowledging that the "extent of [benzene] absorption through the skin is unknown" (Pet. App. 58a). Yet on that fact-bereft basis OSHA banned skin contact with liquids containing only trace amounts of benzene, thereby placing greater limitations on skin contact than on airborne exposure, even though OSHA recognized the only evidence of a carcinogenic hazard from benzene related to inhalation.

Throughout the entire course of the proceedings on the benzene standard, OSHA has ignored, and continues to ignore, the "unrefuted testimony" (Pet. App. 27a, 581 F.2d at 507, 508) of Dr. Howard Maibach as to readily available skin absorption data. Dr. Maibach testified that simple, straightforward and reliable experimental techniques using radioactive-tagged benzene can determine within a short time (six to twelve weeks) whether benzene penetrates the skin and can answer a number of other questions about possible skin absorption. (A. 61-64, 155-157.) A study of the type described (and now completed) by Dr. Maibach was "available" to OSHA

any time the Agency chose to obtain it. Unless OSHA is to be permitted to impose regulations based on "policy" rather than scientific information, the Agency will have to consider valid skin absorption data.

OSHA cannot shift to potentially regulated parties the Agency's own responsibility to obtain the kind of factual, scientific information the Act requires. This case well illustrates what can occur when an agency charged with developing standards based on "research, demonstrations, [and] experiments" promulgates regulations in disregard of available scientific research. OSHA's ban on dermal contact placed rubber companies in the position of having to seek out a university professor to conduct the very research study OSHA should have first obtained, to attempt to disprove the Agency's "policy". At rock bottom, OSHA has asked this Court to shift to regulated parties the task of developing data to disprove on factual grounds standards adopted by the Agency in reliance on "policy."

Respecting the dermal contact issue, this is a record-dependent case, resulting from OSHA's refusal to comply with the evidentiary requirements of the standard-setting sections of the Act. Based on its own careful review of *all* the evidence in the record, the court of appeals properly concluded that the dermal contact sections were not supported by substantial evidence and were not reasonably necessary. Under this Court's decision in *Universal Camera Corp.* v. *National Labor Relations Board*, 340 U.S. 474, 491 (1951), the Court should respect the effort of the court of appeals in reviewing all the portions of the factual record relating to the dermal contact provisions.

ARGUMENT

I. THE COURT OF APPEALS CORRECTLY HELD THAT THE DERMAL CONTACT SECTIONS OF THE BENZENE STANDARD WERE NOT "BASED UPON RESEARCH, DEMONSTRATIONS, [AND] EXPERIMENTS", AS REQUIRED BY THE ACT

A. The Statutory Framework For Standard-Setting And For Judicial Review Of Standards

This case arises procedurally under Section 6(f) of the Act, 29 U.S.C. § 655(f), which provides for judicial review of OSHA standards according to a "substantial evidence" test. Whether there is substantial evidence to support OSHA's action must be determined by reference to the specific requirements of the standard-setting provisions of the Act. The applicable sections of the Act are summarized below.

Section 6(f) of the Act provides that upon review of an OSHA standard by a court of appeals, "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." While courts of appeals have noted the "anomaly in subjecting notice and comment rulemaking . . . to the substantial evidence test" (*Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 347 (2d Cir. 1973)),[29] they have also recognized that the substantial evidence test was the product of a conscious Congressional compromise. As Judge Friendly concluded after reviewing the legislative history of Section 6(f):

> [T]he intention to adopt the substantial evidence test for review as a tradeoff for the House's abandoning its insistence on rulemaking on the record, which would automatically have invoked that test under 5 U.S.C. § 706(2)(E), is apparent. (*Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 349 (2d Cir. 1973).)[30]

[29] *Accord, Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 128 (5th Cir. 1974); *see also Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 473 (D.C. Cir. 1974).

Upon review of a challenged OSHA standard, the Agency "has an affirmative burden to demonstrate the reasonableness of an adopted standard." (*Atlantic & Gulf Stevedores, Inc.* v. *Occupational Safety and Health Review Commission*, 534 F.2d 541, 551 (3d Cir. 1976).[31]

Because the Act prescribes different criteria for the adoption of different types of OSHA standards (such as emergency temporary standards or permanent standards), review of whether an OSHA standard is supported by substantial evidence must necessarily be conducted in the context of the specific standard at issue to "at a minimum determine if the Secretary applied the correct [criteria] . . . ." (*Synthetic Organic Chemical Mfrs.' Ass'n* v. *Brennan*, 503 F.2d 1155, 1160 (3d Cir. 1974).)

The specific standard-setting criteria applicable in this case are enumerated in Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), which mandates that OSHA set standards for toxic materials or harmful physical agents on the basis of the "best available evidence", "research, demonstrations, experiments, and such other information as may be appropriate", and "the latest available scientific data in the field." These specific requirements

[30] *Accord, Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 128 (5th Cir. 1974); *but cf. Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 474-476 (D.C. Cir. 1974) (substantial evidence review for "factual" questions, a different and perhaps lesser review for "policy" issues).

A chronological summary of the legislative history of the standard-setting provisions of the Act is set forth in Addendum B to the API Brief. This discussion, and subsequent discussion of the legislative history, will refer to this Addendum.

The legislative history of Section 6(f) is described in the API Brief, Addendum B, especially at 7b, 12b, 20b-21b.

[31] *Accord, Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 351-353 (2d Cir. 1973).

are supplemented by Section 3(8) of the Act, 29 U.S.C. § 652(8), applicable to all OSHA standards, which defines an "occupational safety and health standard" as one which is "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." [32]

Judicial review of OSHA standards is aided by Section 6(e) of the Act, 29 U.S.C. § 655(e), which requires that whenever OSHA promulgates a standard, the Agency must publish an accompanying "statement of the reasons for such action . . . ." OSHA has fleshed out this provision in its own regulations, which provide that "the statement [of the basis and purpose of a standard] will show the significant issues which have been faced, and will articulate the rationale for their solution." (29 C.F.R. § 1911.18(b).)

Considered together, the foregoing statutory provisions evidence a clear Congressional directive that OSHA standards must be properly premised on a factual, scientific basis. Courts of appeals reviewing challenged OSHA standards have recognized this Congressional mandate. Even the D.C. Circuit, which has given the judicial review provisions an unduly restrictive interpretation when reviewing action by OSHA based on policy,[33] has required

[32] OSHA standards must also be consistent with general purpose of the Act, set forth in section 2(b), 29 U.S.C. § 651(b), "to assure *so far as possible* every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." (Emphasis added.)

[33] *See supra*, at 21 n. 30. The D.C. Circuit in *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 474-476 (D.C. Cir. 1974), suggested that it was not applying a substantial evidence test on review of OSHA action based on "policy" grounds. The court offered no statutory basis for its decision, but rather supplied its own policy-based rationale, *i.e.*, that "policy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions." *Id.* at 475. The difficulty arises more with the court's misuse of this rationale than with the rationale itself. The court in the *IUD* case did not pay

OSHA's factual findings to be supported by evidence, not assumptions or pseudo-scientific speculation. In *Industrial Union Department* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974), the court noted that while some questions may be "on the frontiers of scientific knowledge" where "insufficient data is presently available",

> when the facts underlying the Secretary's determinations are susceptible to being found in the usual sense, that must be done, and the reviewing court will weigh them by the substantial evidence standard. (*Id.* at 474.)

Thus, even when the principal sections of a challenged OSHA standard have been upheld, other sections of the

sufficient heed to that part of the Congressional compromise which mandated detailed judicial review of all of OSHA's "determinations," however based.

Much OSHA "policy" is offered in lieu of factual evidence, as this case illustrates. The reviewing court should give close scrutiny to the record to insure that agency "policy" has not been misused in this way. In addition, the Agency should be required to identify the assumptions it made in adopting its "policy" and to specify the factual support at hand to support those assumptions. In reviewing the actions of other agencies, such as the Environmental Protection Agency, courts have required a comparable identification of assumptions and specification of bases, even where an "arbitrary and capricious" test was applicable on review. *See International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 643-45 (D.C. Cir. 1973); *Tanners' Council of America* v. *Train*, 540 F.2d 1188, 1192-94 (4th Cir. 1976). In *International Harvester* the D.C. Circuit itself explicitly stated that "[i]t is up to EPA, however, *to support its methodology as reliable*, and this *requires more than* reliance on the unknown, either by *speculation, or mere shifting back of the burden of proof*." 478 F.2d at 645 (emphasis added).

In short, while there is an element of truth in the D.C. Circuit's observations in the *IUD* case, that court there allowed itself to be carried too far in its resulting verbal formula for describing its review function regarding agency "policy". Its overstatement gives rise to the prospect that a reviewing court might not give OSHA's action the "close look" which the statute requires to be given. *Compare Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F.2d 120, 129 (5th Cir. 1974); *Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 351-353 (2d Cir. 1973).

standard have been set aside when the requisite factual findings had not been made.[34] This has occurred, for example, when the lack of factual support for a provision in a standard "may be partially attributable to the Secretary's failure to seek it." (*Id.* at 480.)

B. In Adopting The Dermal Contact Sections, OSHA Totally Ignored The Act's Mandate That Permanent Standards Shall Be Developed From Research, Demonstrations, And Experiments

In the face of the specific evidentiary requirements of Section 6(b)(5), OSHA has shown an evident lack of concern for addressing, much less resolving, factual and scientific questions relating to skin absorption of benzene from liquids containing trace amounts of this substance. Throughout the entire course of these proceedings, the issue of skin exposure has been merely a "side issue" to OSHA, which the Agency considered only as an adjunct to the airborne exposure provisions. Indeed the preamble to the benzene standard significantly fails to describe any demonstrated carcinogenic hazard associated with skin contact with liquids containing benzene. (*Compare* Pet. App. 78a-132a (health effects of inhalation).) Similarly, the preamble fails to identify any workplaces where significant skin contact with benzene arises. (*See* Pet. App. 192a-194a.)

In an apparent attempt to mask its own failure to obtain the type of information the statute requires, OSHA now presents this Court with the curious argument that the Act's requirement for "research, demonstrations, [and] experiments" is no requirement at all. Rather, OSHA asserts it has "discretion" to determine whether it is "appropriate" to gather factual information, and that the Agency's discretion is not reviewable under the

[34] *Industrial Union Department* v. *Hodgson*, 499 F.2d 467, 480-481 (D.C. Cir. 1974) (no finding was made respecting inter-industry differences in time needed for compliance).

Act's substantial evidence test, but should be set aside "only on the clearest abuse of discretion". (OSHA's Brief at 82.) Recourse to the language of the Act and its legislative history proves otherwise.[35]

1. *The substantial evidence test applies to all of OSHA's actions in setting standards under the Act.*

Respecting the appropriate standard of review, OSHA's assertions are directly contrary to the clear statement in Section 6(f) that OSHA's "determinations" are to be reviewed for substantial evidence.[36] There are no exceptions. Thus, in a standard-setting context, all of OSHA's determinations underlying the standard under review are subject to the substantial evidence test specified in Section 6(f), including determinations whether or not to seek additional factual data or information. To engraft an

[35] Thus, this is definitely not one of those relatively rare "circumstances when statutory language mandatory in form is [or should be] held to constitute a mere directory command to the agency, so that variance triggers no judicial sanction." *Alabama Power Co.* v. *Costle*, No. 78-1006, slip op. at 33 (D.C. Cir. June 18, 1979).

[36] Congress' action in prescribing a more-stringent-than-usual standard of review is a signal to reviewing courts of appeals not to gloss over problem areas.

More generally, as this Court said in a related context in *Addington* v. *Texas*, 47 U.S.L.W. 4473 (Apr. 30, 1979), a standard of proof has significance to a fact-finder:

> [E]ven if the particular standard-of-proof catchwords do not always make a great difference in a particular case, adopting a 'standard of proof is more than an empty semantic exercise.' *Tippitt* v. *Maryland*, 436 F.2d 1153, 1166 (CA4 1971) (Sobeloff, J., concurring and dissenting), cert. dismissed *sub nom. Murel* v. *Baltimore City Criminal Court*, 407 U.S. 355 (1972). 47 U.S.L.W. at 4475.

For the same reasons, the standard of review here is as important to the reviewing courts of appeals, to the Agency, and to those affected by OSHA's actions.

exception on the Act's judicial review provision would require judicial legislation. Not one jot of statutory language supports such an exception.

Of equal importance, the legislative history of the Act shows that adoption of the substantial evidence test was critical to the Congressional compromise that permitted passage of the Act.[37] Congress was quite concerned that it provide a meaningful judicial check on actions by an administrative agency it feared might establish standards lacking any significant scientific or factual basis.[38] OSHA understandably may not appreciate the value of such a check on its decisions, but Congress acted to provide a check among other things for the very reason OSHA here seeks to avoid it.[39]

2. *Section 6(b)(5) imposes evidentiary requirements for OSHA's permanent standards.*

Section 6(b)(5) states explicitly what is required of the Agency. It provides in part:

> Development of standards under this subsection *shall be* based upon research, demonstrations, experiments, and such other information as may be appropriate." (Emphasis added.)[40]

[37] *See supra*, at 20-21 & nn. 29-30; API Brief, Addendum B at 20b-21b.

[38] *See* API Brief, Addendum B at 6b-7b, 10b-12b, 19b-21b.

[39] The Assistant Secretary of Labor for Occupational Safety and Health, Eula Bingham, recently remarked that OSHA is not "prohibited from doing just about anything we want to do" to protect employees' safety and health, and further stated that adverse judicial decisions will not deter the Agency. Address by Assistant Secretary Bingham to ABA Institute on Law, Science and Technology in Health Risk Regulation (Apr. 20, 1979) reported at [1979] Occupational Safety & Health Reporter, Current Reports (BNA) at 1690. Given that view, perhaps it is not surprising that commentators have criticized the Agency's decisionmaking process. Those commentators have sought to have OSHA "isolate delicate scientific judgments from the rough and tumble of political pressure and the temptation to bend scientific testimony for regulatory expedience—a temptation that OSHA, together with other agencies, has already shown signs of succumbing to." FORTUNE, July 3, 1978, at 90.

This language of mandate is in sharp contrast to the discretionary authority given to OSHA later in the same section, to express standards in terms of objective criteria and desired performance "[w]henever practicable".

The Act's legislative history is equally clear that Congress intended in Section 6(b)(5) to impose specific evidentiary requirements on OSHA as part of the standard-setting process.[41] Special standard-setting criteria for occupational health standards were first proposed by the House Committee on Education and Labor (the "House Committee"), to take account of the somewhat different problems presented by occupational health hazards.[42] Un-

[40] The comma after the word "experiments" suggests that the phrase "as may be appropriate" was intended to modify only "such other information". OSHA's argument to the the contrary (OSHA's Brief at 82 n.67) is based only on a quotation from a report of the Senate Committee on Labor and Public Welfare. In its report, the Senate Committee stated its intention that standards promulgated under Section 6(b) be feasible requirements "which, where appropriate, shall be based on research, experiments, demonstrations, past experience, and the latest available scientific data." Subcomm. on Labor of the Senate Comm. on Labor and Public Welfare, 92d Cong., 1st Sess., *Legislative History Of The Occupational Safety And Health Act of 1970* (Comm. Print 1971), at 147 [hereinafter "Leg. Hist."]. The quoted language was part of a section-by-section summary of the major provisions of S.2193, which summary purported only to restate the provisions and not to interpret them. Under OSHA's argument, it would also have discretion as to whether to consider "past experience" and the "latest available scientific data", even though the text of Section 6(b)(5) is equally categorical as to consideration of those factors (*e.g.*, "[o]ther considerations *shall be* the latest available scientific data . . ." (emphasis added)).

[41] API Brief, Addendum B, 10b-11b.

[42] API Brief, Addendum B at 6b-7b, 10b-11b, 19b.

der the bill adopted by the House Committee, OSHA would have been allowed to set standards under informal notice-and-comment rulemaking procedures, "on the basis of the best available professional evidence." [43] Although adopted by the House Committee, this provision evoked bitter complaints from minority members of the Committee. In particular, the minority denounced the bill for allowing standards to be based on " 'views and arguments' rather than probative evidence",[44] and objected to the majority's rejection of formal rulemaking procedures for setting standards.[45]

The concerns of the House Committee minority were, however, heeded when the Senate Committee on Labor and Public Welfare (the "Senate Committee") considered S. 2193 in the fall of 1970. Although the Senate Committee had for the most part developed the bill independently, it specifically chose to follow the approach adopted by the House Committee of providing explicit criteria for setting health standards.[46] Furthermore, as part of key amendments obtained by minority members of the Senate Committee, a number of additional requirements were engrafted onto the House Committee's language. The added requirements emphasized the need for OSHA to develop scientific and factual bases for its standards. As redrafted by the Senate Committee, Section 6(b)(5) read as follows:

[43] Leg. Hist. 943; API Brief, Addendum B at 3b-5b. It was with respect to this early formulation of the standard-setting criteria of Section 6(b)(5) that the House Committee made the statement, on which OSHA so heavily relies (OSHA's Brief at 76), that "it is not intended that the Secretary be paralyzed by the debate surrounding diverse medical opinions." Leg. Hist. 848; API Brief, Addendum B at 6b n. 7.

[44] Leg. Hist. 884 (House Report, Additional Minority Views of Reps. Scherle *et al.*); API Brief, Addendum B at 6b-7b.

[45] Leg. Hist. 879.

[46] API Brief, Addendum B at 7b.

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately *and feasibly* assures, on the basis of the best available [professional] evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. *Development of such standards shall be based on research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.*[47]

These changes served several important purposes. By requiring that standards be "based upon research, demonstrations, experiments, and . . . other information", the Committee expressed its intent that OSHA develop scientifically-based, factually supported standards. The "research, demonstrations, [and] experiments" requirement thus represented an important substantive addition to the House Committee provision, which House minority members had objected would have allowed OSHA to issue standards based on "views and arguments". (*See supra*, at 28.)

The Senate Committee's amendment to Section 6(b)(5) focused attention on the central role of scientific research in the development of standards, and the Committee's intent that OSHA take full advantage of the latest avail-

[47] S.2193 (as reported) 91st Cong., 2d Sess. § 6(b)(5) (1970), Leg. Hist. 242 (new material indicated by italics; deleted material in brackets). The last sentence of the section, which is identical to the last sentence of the House Committee section, is not reproduced in the quoted text.

able data and scientific techniques. At the same time, there was no indication of concern that requiring OSHA to act on the basis of research and factual information would in any way "paralyze" the Agency.[48] To the contrary, the language of the amendment indicates the Senate Committee viewed the requirement that OSHA act on a scientific and factual basis as being wholly consistent with "the attainment of the highest degree of health and safety protection for the employee."

The Senate Committee's amendment emphasizing the need for scientific research in setting standards meshed with the "research" provisions which were already in the Committee bill. Those "research" provisions, which appeared in similar form in *every* occupational safety and health bill introduced in the 91st Congress,[49] directed the Secretary of Health, Education and Welfare to "conduct

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[48] The statement relied on by OSHA (OSHA's Brief at 76) and the IUD (IUD's Brief at 17)—that it was not intended that OSHA be "paralyzed" by medical debate (Leg. Hist. 848)—came in an early House Committee Report which was issued before the Senate Committee significantly amended the House Committee version of Section 6(b)(5). Notably, the House rejected the bill reported by its Committee. Moreover, the Senate Committee apparently disagreed with the House Committee regarding whether evidentiary requirements would paralyze OSHA's standard-setting efforts, because the Senate Committee added specific evidentiary requirements to its version of Section 6(b)(5), which reached well beyond the provision reported by the House Committee (Section 7(a)(4) of H.R. 16785, Leg. Hist. 943). Finally, and most importantly, the specific evidentiary requirements of Section 6(b)(5) were part of the Act as adopted by both Houses of Congress.

[49] *Every* occupational safety and health bill included in the Senate Committee print of the legislative history of the Act (*supra*, at 27 n. 40): (1) included as one of its specific purposes to provide for research in the field of occupational safety and health; (2) directed the Department of Health, Education and Welfare to conduct research; and (3) specifically authorized the Secretary of Labor to contract for research or other studies. S.2193 (as introduced), §§ 2(b)(3), 15, Leg. Hist. 2, 23-24; S.2788, §§ 2(b)(4), 17, Leg. Hist. 33, 63-65; S.4404, §§ 2(b)(5), 23, Leg. Hist. 75, 126-128; S.2193 (as reported), §§ 2(b)(2), 18, 19, Leg. Hist. 234, 274-282; S.2193 (as passed by Senate), §§ 2(b)(2), 19, 20, Leg. Hist. 530, 574-582; H.R. 843, §§ 2(b)(3), 15, Leg. Hist. 600, 621-623; H.R. 3809, §§ 2(b)(3), 15, Leg. Hist. 630, 651-652; H.R. 4294, §§ 2(b)(3), 15, Leg. Hist. 661, 672-673; H.R. 13373, §§ 2(b)(4), 17, Leg. Hist. 681, 711-713; H.R. 16785 (as introduced), §§ 2(b)(3), 19, Leg. Hist. 722-723, 753-757; H.R. 19200, §§ 2(b)(5), 23, Leg. Hist. 765, 816-818; H.R. 16785 (as reported), §§ 2(b)(3), 19, Leg. Hist. 832, 841-842; H.R. 16785 (as passed by House), §§ 2(b)(5), 23, Leg. Hist. 1092, 1107-1108.

. . . research, experiments, and demonstrations relating to occupational safety and health",[50] and created a new National Institute of Occupational Safety and Health ("NIOSH") to perform those functions.[51] A separate section of the Committee bill authorized the Secretary of Labor (OSHA) to enter into contracts with public or private organizations "for the purpose of conducting studies related to the establishing and applying of occupational safety and health standards . . . ." [52]

While the Senate Committee bill was the subject of debate and further modification by the full Senate, no change was made in the requirement that standards be developed "based upon research, demonstrations, [and] experiments".[53] And only a clarifying change was made in the "research" provisions of the bill.[54]

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[50] Leg. Hist. 274; *see id.* at 274-278.

[51] *Id.* at 279-282. NIOSH was established in the Department of Health, Education and Welfare ("HEW").

[52] S.2193 (as reported), 91st Cong., 2d Sess. § 18(b) (1970), Leg. Hist. 277; API Brief, Addendum B at 11b n. 15. Apparently in recognition that the research activities contracted for by OSHA might often be different from and supplementary to those of NIOSH, OSHA was directed to cooperate with HEW (of which NIOSH is part) "to avoid any duplication" of research efforts. *Id.*

[53] An amendment was adopted that left no doubt that the second and third sentences of Section 6(b)(5) apply to all permanent standards, including safety standards. The introductory phrase of the second sentence of Section 6(b)(5) was changed to refer to "standards under this subsection", *i.e.*, subsection (b) of Section 6, which prescribes how OSHA is to "promulgate . . . any occupational safety or health standard." Leg. Hist. 502; API Brief, Addendum B at 17b n. 18.

[54] Section 19(b)(2) of S.2193 (as passed by the Senate) was clarified to state that HEW should develop criteria "dealing with toxic materials and harmful physical agents . . . ." Leg. Hist. 575. The same language was added in the clarifying amendment to the first sentence of Section 6(b)(5). Leg. Hist. 538; API Brief, Addendum B at 16b-17b.

In the Senate-House Conference, the Senate provision, with its detailed criteria for setting standards dealing with toxic materials or harmful physical agents, was adopted, although the House prevailed in its insistence upon the stricter substantial evidence test for judicial review.[55] The Senate versions of the "research" provisions (Sections 20 and 22 of the Act) were also adopted.[56] The House prevailed with respect to its statement of the Act's purposes, which though consistent with the Senate statement of purposes, was "more detailed" [57] and emphasized more strongly the important role of research in the proper implementation of the Act.[58]

The picture that emerges from a review of the legislative history is that in Section 6(b)(5) Congress intended that OSHA would set standards based upon scientific evidence rather than "views and arguments".[59] The resulting specific statutory mandate that OSHA standards "shall be based upon research, demonstrations, [and] experiments" is directly contrary to OSHA's assertion

[55] API Brief, Addendum B at 20b-21b.

[56] Leg. Hist. 1174-1178, 1195-1196.

[57] Leg. Hist. 1185; API Brief, Addendum B at 20b n. 21.

[58] Those House provisions, now Sections 2(b)(5) and (6) of the Act, state that the overall purpose of the Act is to be achieved, *inter alia*, "by providing for research in the field of occupational safety and health" and "by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety".

The Conference Committee also adopted the broader House provision authorizing the Secretary (in Section 20(c) of the Act) to contract for studies relating to all of his responsibilities under the Act, rather than only with respect to his standard-setting responsibilities.

[59] Leg. Hist. 884. *See supra*, at 28, 29; API Brief, Addendum B at 6b-7b, 10b-11b.

that it has virtually unbridled discretion to determine whether it is "appropriate" to obtain factual information.[60] Moreover, Congress not only emphasized the importance of research activities to proper fulfillment of the Act's objectives,[61] but also provided OSHA itself with the means to obtain necessary factual information through the "research" provisions of the Act.[62]

3. *The record contains no significant scientific or factual basis for OSHA's dermal contact ban.*

OSHA's own statement of its reasons for the ban on dermal contact, recounted previously,[63] is startling for its lack of any significant scientific or factual basis. A provision of a standard which is based on "extremely limited" record evidence, "few studies" which are "not definitive", and OSHA's "policy" (Pet. App. 192a-193a) cannot be what Congress intended in Section 6(b)(5).[64] Yet OSHA nevertheless banned skin contact with liquids containing even trace amounts of benzene, thereby placing

[60] Even under OSHA's convoluted reading of the "research, demonstrations, [and] experiments" requirement, the Agency's determination not to obtain scientific data of the type suggested by Dr. Maibach and instead to regulate based on the scant information before it can hardly be described as "appropriate".

[61] Sections 2(b)(5) and (6) of the Act, 29 U.S.C. §§ 651 (b)(5), (6).

[62] Sections 20(a)(1), 20(c) and 22 of the Act, 29 U.S.C. §§ 669 (a)(1), (c), 671.

[63] *See supra*, at 7, 13.

[64] OSHA's stated basis for its ban on dermal contact fails even to live up to the Agency's own regulation requiring that any standard will be accompanied by a statement which "will show the significant issues which have been faced, and will articulate the rationale for their solution." 29 C.F.R. § 1911.18(b); *see supra*, at 22. OSHA standards have been set aside for failure to satisfy this requirement. *Dry Color Mfrs. Ass'n* v. *Department of Labor*, 486 F.2d 98 (3d Cir. 1973); *Associated Industries, Inc.* v. *Department of Labor*, 487 F.2d 342, 353 (2d Cir. 1973).

greater limitations on skin contact than on airborne exposures to benzene, even though the Agency recognized the only evidence of a carcinogenic hazard from benzene related to inhalation.[65]

From the outset, in proposing the benzene standard, OSHA candidly admitted that "studies indicate benzene is not readily absorbed through intact skin." [66] No significant contrary evidence regarding skin absorption was presented during the rulemaking proceeding on the standard.[67] Dr. Howard Maibach, Professor of Dermatology

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[65] An employer is exempt from many of the standard's requirements if workers' exposure to airborne concentrations does not exceed the "action level" of 0.5 ppm. *See* 29 C.F.R. §§ 1910.1028(b), (e)(3), Pet. App. 35a, 37a-38a. Rather than regulate consistently and provide an "action level" for dermal contact, OSHA banned skin contact completely. During the rulemaking proceeding on the amendments to the benzene standard, rubber companies urged adoption of such a "dermal action level" and provided evidence in support of such a provision. *See supra*, at 10-12 & nn. 18-20.

[66] 43 *Fed. Reg.* 27451, 27470 (May 27, 1977), Ex. 4.

[67] The only testimonial references in the record suggesting that benzene can be absorbed through the skin are found in cryptic remarks by two NIOSH witnesses. In response to a question as to whether they had "*any feeling* as to whether . . . dermal exposure is a contributing factor" (A. 40 (emphasis added)), the NIOSH witnesses stated that benzene can be absorbed through the skin. A. 40. As the court of appeals noted, however, "[e]xcept for a passing reference to what appears to be the 1961 positive study, these witnesses did not attempt to support their opinions by empirical data." Pet. App. 25a, 581 F.2d at 506.

These NIOSH witnesses apparently were even unaware of the existence of the reliable experimental technique of using radioactive-tagged benzene to measure definitively whether benzene penetrates the skin. Dr. Laigo of NIOSH testified:

> To what extent [benzene] would be absorbed in any particular exposure, you really don't know. *You can't measure that.* A. 40 (emphasis added).

The court of appeals thus properly determined that these remarks did not constitute evidence, let alone creditable evidence. Pet. App. 25a, 581 F.2d at 506.

at the University of California Medical Center, was the only witness participating in the original rulemaking proceeding [68] who reviewed in detail the state of scientific knowledge regarding skin absorption of benzene. (A. 58-77, 149-157.) Dr. Maibach concluded that:

> Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests it does. (A. 61.)

Dr. Maibach went on to say, however, that modern analytic techniques using radioactively-tagged Carbon-14 benzene can now provide conclusive answers regarding whether benzene is absorbed through the skin and the amount of any absorption. He stated:

> This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would tell us definitely, without argument, and efficiently, just how much of [sic—"if"] any benzene penetrates the skin. (A. 62.)

Dr. Maibach further testified that this experimental procedure could answer a number of other questions about possible skin absorption, that the necessary tests could be completed within six to twelve weeks, and that the tests could be done by anyone having the requisite analytic facilities for radioactively-tagged materials. (A. 61-64, 155-157.)

Dr. Maibach has now completed his skin absorption study. The results have been provided to OSHA.[69]

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[68] Dr. Maibach was called as a witness by the American Petroleum Institute.

[69] Dr. Maibach's study and results are set out in two technical reports, one dated January 19, 1979, and the other dated July 2, 1979. Dr. Maibach's first report was submitted to OSHA on January 22, 1979 and is reprinted as Appendix 1 to the rubber companies' Joint Memorandum in Opposition to the petitions for certiorari. Dr. Maibach's second report was furnished to OSHA on

OSHA to date apparently has not re-examined its ban on dermal contact in light of this careful study. Instead OSHA has attempted to resist application of the results of Dr. Maibach's study (at least insofar as set out in Dr. Maibach's first report) to the absorption issue in the benzene standard proceedings, and to argue that scientific information of the type provided by Dr. Maibach was not "available" at the time OSHA adopted or amended its standard. (*See* OSHA's Brief at 75-81.)

Dr. Maibach's study is itself not part of the record before this Court.[70] What *is in the record* is testimony in 1977 by Dr. Maibach regarding the nature of such a study, the information obtainable from it, and the time required for its completion (A. 61-64, 155-157), along with the added information, put before OSHA in 1978 at the time of the proceedings to amend the standard, that Dr. Maibach was actually going to carry out the study (Amend. Tr. 71-73).

Importantly, Dr. Maibach's study does not represent "one more study", and thus impliedly just a delaying

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July 9, 1979. A copy of the second report has been lodged with the Clerk in the event this Court should wish to have access to it.

In important part, Dr. Maibach's study found that only minute percentages of pure benzene or benzene contained in rubber solvents applied to the skin of rhesus monkeys were absorbed through the skin. This was so even with multiple doses approximating chronic exposures, and with "damaged" skin (*i.e.*, skin from which the *stratum corneum* had been completely removed).

Based on certain highly conservative assumptions, Dr. Maibach concluded that in passenger tire building the amount of benzene absorbed from skin contact with solvent containing benzene is a fraction of the amount of benzene permitted to be inhaled at 1 ppm. *See also supra*, at 12 n. 20 (referring to Dr. Johnson's comparative study of routes of possible exposure, relying on Dr. Maibach's work for the dermal aspect of the comparison).

[70] For that reason rubber companies do not here respond to OSHA's asserted deficiencies in Dr. Maibach's study. Rubber companies do not, however, agree with OSHA's assertions, and will respond to them at such time as OSHA actually considers on the merits the issue of skin absorption of benzene and liquids containing small amounts of benzene.

tactic by parties about to be subjected to government regulation, as OSHA would have this Court believe. (*See* OSHA's Brief at 81.) Rather, Dr. Maibach's work now constitutes the only valid skin absorption study of benzene in OSHA's possession. OSHA did not have any significant scientific data relating to skin absorption of benzene when it proposed the benzene standard in 1977, and, apart from Dr. Maibach's study, it has not generated or received any such data since that time. Unless this Court sanctions OSHA's imposition of regulations based on a fact-bereft "policy" rather than upon scientific information, the Agency will have to consider Dr. Maibach's absorption study.

OSHA's argument that Dr. Maibach's study was not available to it is equally without merit.[71] The "unrefuted testimony" during the hearings on the original proposed standard is that anyone with the analytic facilities available could have completed the tests in six to twelve weeks. (Pet. App. 26a-27a, 581 F.2d at 507, 508.) When in the hearings in the proceedings to amend the standard, the rubber companies reported that Dr. Maibach was then going forward with the study, the Director of OSHA's Health Standards Programs again stated that the Agency would act in the absence of the study's results. (A. 185.)

The benzene standard has never gone into effect. Because of this circumstance, the rubber companies did not press Dr. Maibach to complete the study within the six-to-twelve week period he testified would be needed for the study. Instead, Dr. Maibach has conducted his experiments without reference to a time objective. The experiments comprising the study were accomplished with first priority given to his teaching schedule and other research projects. Nonetheless, the total elapsed working time actually spent in conducting Dr. Maibach's experiments has been less than twelve weeks. Of course, of greater importance now is the circumstance that the absorption data actually has been obtained.

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[71] Again, OSHA could consider the study now, if it chose to do so.

4. *OSHA cannot shift to regulated parties the task of developing data to disprove on factual grounds standards adopted in reliance on "policy".*

OSHA cannot shift to regulated parties its own responsibility to obtain the kind of information the statute requires. (*See* OSHA's Brief at 77 n. 61.) Section 6(b)(5) requires *the Agency* to act on the basis of "research, demonstrations, [and] experiments", and the Act's "research" provisions give OSHA the means of doing so. Scientific evidence relating to skin absorption was available any time OSHA chose to obtain it. OSHA has represented to this Court that it has "a substantial scientific staff and a decade's experience in the administration of toxic substances regulation" (OSHA's Brief at 66-67), and also that "questions concerning the extent of absorption of benzene into the body through exposed surfaces were *obvious candidates* for research." (OSHA's Brief at 77 n. 61 (emphasis added).) Given OSHA's conceded lack of evidence respecting skin absorption (*see supra*, at 7, 33-34), the Agency should have obtained scientific information on this issue prior to proposing the dermal portions of the standard. OSHA could have gathered the data either through use of NIOSH's extensive research capabilities,[72] or by contracting with scientists or research organizations.[73]

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[72] Section 20(a)(1) of the Act, 29 U.S.C. § 669(a)(1), provides that "[t]he Secretary of Health, Education and Welfare, *after consultation with the Secretary [of Labor]*, . . . shall conduct (directly or by grants or contracts) *research, experiments and demonstrations relating to occupational safety and health* . . ." (emphasis added). NIOSH is generally to perform these and other functions of the Secretary of Health, Education and Welfare under the Act. 29 U.S.C. §§ 669(e), 671(a). The general scope of NIOSH's activities is set forth in 29 U.S.C. §§ 669, 671.

[73] OSHA has not hesitated to use outside consultants when it suits the Agency's purposes. For example, in the hearing in the original benzene prcoeeding, OSHA called various scientific witnesses, as well as NIOSH witnesses, to present new evidence and to review existing scientific evidence relating to the airborne exposure provisions of

At a minimum, OSHA could have given industry adequate notice of the Agency's intention to ban dermal contact with liquids containing even trace amounts of benzene, so that affected parties such as the rubber companies could have conducted skin absorption studies.[74] In any event, OSHA was explicitly informed both of the outdated and inconclusive nature of its existing data and of the availability of reliable experimental techniques to obtain needed data when Dr. Maibach testified before the

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the standard. Had it chosen to do so, the Agency could have contracted for a review of scientific methods relating to skin absorption, so that it would have been aware of the straightforward and reliable research techniques as to which Dr. Maibach testified.

In a subsequent proceeding (Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 *Fed. Reg.* 54147-54247, Oct. 4, 1977), OSHA contracted with numerous scientific witnesses, at a cost of many thousands of dollars, to present scientific evidence (including voluminous literature citations) relating to specific provisions of its proposal. In the same proceeding, OSHA engaged an outside contractor to review and advise the Agency on a wide variety of scientific, economic and other technical aspects of the proposal. It has been reported that OSHA had paid that contractor "close to $400,000" as of November 1978. 88 Cong. Rec. H5417 (daily ed. June 28, 1979).

[74] As described in rubber companies' Joint Memorandum in Opposition to the petitions for certiorari (at 9-12, 26-30), and as discussed in detail in rubber companies' brief filed with the court of appeals (Joint Brief for Rubber Companies, *et al.* (May 8, 1978), at 4-8, 12-15, Amend. Ex. 96), both the ETS and the proposed standard included a "percentage exclusion" totally exempting from the standard's coverage materials with less than a specified benzene content. *See supra*, at 5-6 & n. 10. When OSHA issued its original standard covering any material with any benzene content, in contrast to its previous position and without any express notice, its action came as a surprise, at least to rubber companies.

OSHA admits to having been put on notice by rubber companies in the original rulemaking proceeding that the dermal contact provisions were "overly restrictive", "impractical", and "burdensome and disruptive of the manufacturing process." Brief for the Secretary of Labor (before the court of appeals) (June 1978), at 100 n. 93.

Agency on August 3, 1977. (A. 58-77, 149-157.)[75] OSHA could easily have arranged for the necessary experiments to be completed in the six months which elapsed before the standard was promulgated in February, 1978.

OSHA unblushingly now argues that the passage of the Act in 1970 should have put rubber companies on notice that the Agency would act as it did in 1978. OSHA asserts:

> The statute itself put industry on notice that toxic substances are subject to regulation, and it was common knowledge that benzene is toxic. . . . Industry could have begun the process of research [relating to skin contact with benzene] as soon as the statute was enacted; it did not need to wait until the initial notice of rulemaking. (OSHA's Brief at 77 n. 61.)

OSHA's argument *could be* correct only if rubber companies and others *in 1970* could have foreseen: that OSHA would in 1977 select benzene from among the more than 26,000 toxic substances[76] as a candidate for further regulation; that after proposing an exemption for mixtures containing small amounts of benzene, OSHA would in its final standard prohibit all skin contact with mixtures containing any amount of benzene; that OSHA's ban on

[75] OSHA presumably was aware before 1977 of the reliable experimental technique of using materials "labeled" with radioactive carbon (^{14}C). The Assistant Secretary of Labor for OSHA, Dr. Eula Bingham, reported in 1974 on an experiment in which ^{14}C-labeled benzo[a]pyrene (BaP) was used. R. W. Niemeier and E. Bingham, *Distribution of Metabolites of Benzo[a]pyrene in the Isolated Perfused Rabbit Lung Preparation*, 29(1) Toxicol. Appl. Pharmacol. 93-94 (1974) (abstract).

[76] I NIOSH, REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES xiii (1977 ed., Sept. 1977) (26,478 toxic chemical compounds). NIOSH has published a list of 2,415 potential occupational carcinogens, of which 1,905 substances "were selected on the basis of reported neoplastic or carcinogenic effects." NIOSH, SUSPECTED CARCINOGENS: A SUBFILE OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES, foreward (2d ed. Dec. 1976).

dermal contact would be adopted based on OSHA's "policy" and without any significant factual support; and that after banning dermal contact, OSHA would persist in disregarding available research data relating to skin absorption. Although OSHA may consider the passage of the Act to be sufficient "notice" of the Agency's intentions, the statute requires evidence, not this type of "notice," to support standards.

Given the explicit testimony and comment received by the Agency during its administrative proceedings, OSHA cannot support its decision to regulate dermal contact in ignorance of scientific information of the type the Act both *requires* and *enables* the Agency to obtain. An agency charged with developing standards on the basis of "research, demonstrations, [and] experiments" must consider available scientific research. As a general matter, OSHA, prior to proposing standards, should evaluate initially whether factual evidence and research data in its possession are sufficient to support its contemplated regulatory action, whether gaps exist in this information, and whether other data are readily available to fill any gaps in information and to confirm or deny such information. Where, as here, scientific research can promptly fill informational gaps, the requisite research studies can readily be obtained.[77]

OSHA itself has recognized the need to follow such a scientific approach; the Agency's proposed generic carcinogen standard would permit OSHA to delay for up to 180 days publication of information relating to the classification of a toxic substance where:

[77] Other cases may pose different issues, especially where the research or experiments cannot be carried out within such a short time. This case does not, for example, raise the same issues which would arise where the needed data or information cannot be obtained without work over 12-18 months or even several years. Presumably where OSHA faces such a situation it must weigh factors such as the immediacy of need for regulatory action and the importance to the regulatory situation of the information.

> information exists that additional scientific data or study that may be relevant to the classification of a toxic substance is not immediately available or does not yet exist but will be available within a short period of time. (42 Fed. Reg. 54147, 54184 (Oct. 4, 1977).)[78]

The use by other scientific regulatory agencies of outside research facilities and consultants to obtain needed scientific data is widespread.

Nonetheless, as Judge Bazelon recently observed, "if there is no commitment to a candid exploration of the issues, the predicate for good decisionmaking will be lacking."[79] Judge Bazelon's observation aptly describes OSHA's action in this case. Relying on its "policy" (Pet. App. 192a), the Agency promulgated a ban on dermal contact "which would require an established industry to change long-followed work practices that are not demonstrably unsafe." (Pet. App. 27a, 581 F.2d at 508.) Rubber companies were placed in the position of having had to seek out a university professor to conduct the very research studies OSHA should have first obtained, in order to attempt to disprove the Agency's "policy". Where the burden of supporting its standards by substantial

[78] This 180-day period proposed by OSHA provided the time period for the hypothetical question posed to OSHA's Director of Health Standards Programs during the hearing on the amendment to the benzene standard. That question was whether OSHA would change its projected timetable for adopting the amendment if the results of a skin absorption study of the type being conducted by Dr. Maibach "could be made available to OSHA within 180 days". A. 184-185. OSHA's Director responded: "No, sir." A. 185; *see supra*, at 10. Contrary to OSHA's assertion, rubber companies did not request OSHA "to reopen the record and stay the standard for 180 days . . . ." OSHA's Brief at 77 n. 61. Indeed, the benzene standard had previously been stayed by the court of appeals. *See supra*, at 9 n. 13.

[79] "Risk and Responsibility", Address by Circuit Judge David L. Bazelon, ABA National Institute on Law, Science and Technology in Health Risk Regulation, ABA Section of Science and Technology (Apr. 20, 1979), at 12, reprinted in SCIENCE, July 20, 1979, at 280.

evidence has been placed with OSHA, industry parties should not be "confronted with the often-formidable task of establishing a 'negative averment'." (*International Harvester Co.* v. *Ruckelshaus*, 478 F.2d 615, 643 (D.C. Cir. 1973) (quoting *United States* v. *Denver & Rio Grande R.R.*, 191 U.S. 84, 92 (1903).)

C. OSHA Cannot Now Justify Its Ban On Dermal Contact By Post Hoc Rationalizations

Faced with the findings of the court below that its ban on dermal contact was neither supported by substantial evidence, as required by Section 6(f) of the Act, 29 U.S.C. § 655(f), nor "reasonably necessary" within the meaning of Section 3(8) of the Act, 29 U.S.C. § 652(8), OSHA's Brief attempts to provide new explanations of the reasons for the Agency's action. (OSHA's Brief at 27-28.) The explanations by OSHA's lawyers, advanced for the first time before the court of appeals[80] carry no weight:

> It has long been settled that in reviewing an agency action and the adequacy of an agency's articulation of its action, including findings of fact and reasoning processes, courts must look to the record that was considered by the agency and to the factual findings and reasoning of the agency—not to *post hoc* rationalizations of counsel or even agency members . . . ." (*Dry Color Mfrs.' Ass'n* v. *Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973).)[81]

[80] Similar assertions as to the basis for OSHA's action first appeared in OSHA's briefs to the court of appeals. They were reiterated and embellished in OSHA's Reply Memorandum in support of its petition for certiorari. Reply Memorandum for Petitioner in No. 78-1036, Feb. 1979, at 4-5.

[81] *See supra*, at 15-16 & n. 26. As stated in *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council*, 435 U.S. 519, 549 (1978), this Court has:

> made it abundantly clear before that when there is a contemporaneous explanation of the agency decision, the validity of that action must "stand or fall on the propriety of that finding, judged, of course, by the appropriate standard of review. If that finding is not sustainable on the administrative record

The court of appeals followed this principle and on the basis of *all* the evidence in the record set aside the dermal contact sections. The court below specifically rejected as a "post hoc rationalization" OSHA's attempt to justify the dermal contact sections out of a concern for dermatitis.[82] This Court should similarly reject OSHA's eleventh-hour attempt to "bootstrap" support for its action.[83]

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made, then the [agency's] decision must be vacated and the matter remanded [to the agency] for further consideration." *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973). See also *SEC* v. *Chenery Corp.*, 318 U.S. 80 (1943).

[82] OSHA persists in arguing to this Court that the dermal contact sections were based on a concern for dermatitis. OSHA's Brief at 28, 82-83 n. 67. Even if that were the case, as the court of appeals specifically found it was not (Pet. App. 22a-23a, 581 F.2d at 505-506), exposure limits of a regulation developed to protect against cancer are a grossly inappropriate method for dealing with dermatitis. A concern for dermatitis cannot reasonably support a requirement that all containers containing any amount of benzene be labeled as a "CANCER HAZARD". *See* 29 C.F.R. § 1910.1028(b), (c)(2), and (k)(2)-(4), Pet. App. 35a-36a, 42a, 47a-48a, and *supra*, at 6 n. 11. The record contains little evidence respecting a risk of dermatitis. More importantly, however, *after* OSHA issued the benzene standard the Agency formed an advisory committee to deal directly with problems of skin hazards, including dermatitis. On March 14, 1978, OSHA announced formation of an ad hoc advisory committee to "identify the occupational exposures in industry which pose a hazard to the skin and/or use of the skin as a portal of entry" and to "provide OSHA with a set of guidelines to use in the drafting of a proposed standard on cutaneous hazards". 43 *Fed. Reg.* 10647-10648 (Mar. 14, 1978).

[83] OSHA's newly proferred justifications for its ban on dermal contact seriously overstate the record evidence in a number of respects. Several examples suffice.

Quoting the one study in the record that found any skin absorption of benzene, OSHA asserts that "the view is generally accepted that [benzene] has the ability to be absorbed through the skin . . . ." OSHA's Brief at 27. However, the sentence being quoted from the study continues:

> *but to an extent which does not induce intoxication. It is also accepted in practice that the sole essential path of benzene absorption under industrial conditions is the lungs.* A. 107 (emphasis added).

That study, which OSHA admits is not "definitive" (OSHA's Brief at 27 n. 29), and whose methodological deficiencies were discussed in detail by Dr. Maibach (A. 60-61, 152-155), concluded in 1961 only that "the absorption of benzene throughout [sic] the skin must not be neglected." A. 120. As the court of appeals observed, "the 1961 study reporting positive results used a technique, compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin." Pet. App. 24a, 581 F.2d at 506.

OSHA asserts that "[e]xperiments show skin absorption of benzene in animals", citing, among other things, a study in the record (Ex. 2-46 at 1-2, A. 95-96). OSHA's Brief at 27. OSHA's reference is to the introductory section of that study, in which the authors review earlier (pre-1955) studies. The study itself (Ex. 2-46) concludes that the "possibility of a percutaneous passage of benzene in the experimental conditions adopted is therefore *rejected*." A. 100 (emphasis added).

OSHA speculates that benzene "*may* be absorbed through damaged skin" (OSHA's Brief at 27 (emphasis added)), quoting Dr. Maibach's testimony that it is "ordinarily assumed that penetration of any molecule will be greater through damaged skin . . . ." A. 64-65. In the same sentence, Dr. Maibach went on to say:

> *but unfortunately I have to tell you that today that is usually as [sic] assumption rather than a fact, . . . we have almost no background data to verify that assumption, and it could be that when we get the data, it may be very surprising.* A. 64 (emphasis added).

OSHA represents to this Court that where benzene is present in solvents, the solvents can "result in or increase the extent of skin absorption of benzene." OSHA's Brief at 28. OSHA cites as authority its own preamble to the benzene standard, which contains an unsupported statement to the same effect. Contrary to OSHA's statement, Dr. Maibach's first report, which was submitted to OSHA in January 1979, found that proportionally *less* benzene was absorbed when contained in rubber solvent than when 100 percent benzene was used. Rubber companies' Joint Memorandum in Opposition to the petitions for certiorari (Jan. 26, 1979), App. 1 at 9a.

OSHA states it is "advisable to guard against dermal contact in order to [facilitate compliance with the airborne exposure provisions]." OSHA's Brief at 28. Even at this late date, OSHA persists in its focus on airborne exposure, failing to recognize that even despite compliance by rubber companies with airborne exposure limits, they cannot avoid dermal contact in their operations.

II. THIS COURT SHOULD NOT DISTURB THE COURT OF APPEALS' FINDINGS THAT THE DERMAL CONTACT SECTIONS WERE NOT SUPPORTED BY SUBSTANTIAL EVIDENCE AND WERE NOT REASONABLY NECESSARY

Respecting the dermal contact sections, this is a record-dependent case, relating to OSHA's failure to comply with the evidentiary portions of the standard-setting provisions of the Act. Recognizing that whether there was substantial evidence supporting the dermal contact sections could be determined only on the basis of the particular facts shown on the record before it, the court of appeals conducted a careful and thorough review of the record (Pet. App. 22a-27a, 581 F.2d at 505-508), consistent with its statutory obligation to review closely OSHA's actions. Based on all the evidence in the record, the court below properly concluded that the dermal contact sections were not supported by substantial evidence and were not reasonably necessary.

As this Court stated in *Universal Camera Corp.* v. *National Labor Relations Board*:

> Whether on the record as a whole there is substantial evidence to support agency findings is a question which Congress has placed in the keeping of the Courts of Appeals. This Court will intervene only in what ought to be the rare instance when the standard appears to have been misapprehended or grossly misapplied. (*Universal Camera Corp.* v. *National Labor Relations Board*, 340 U.S. 474, 491 (1951).)[84]

[84] *Accord, Mobil Oil Corp.* v. *Federal Power Commission*, 417 U.S. 283 (1974); *Central Hardware* v. *National Labor Relations Board*, 407 U.S. 539 (1972); *see also National Labor Relations Board* v. *Baptist Hospital, Inc.*, 47 U.S.L.W. 4789, 4791-4793 (opinion of the Court) and 4794 (Brennan, J., concurring in the judgment) (June 20, 1979).

OSHA has not "met its burden of demonstrating that the Court of Appeals misapprehended or grossly misapplied the substantial evidence standard" (*Mobil Oil Corp.* v. *Federal Power Commission*, 417 U.S. 283, 330 (1974)), and thus this Court should respect the effort of the court of appeals in going through all the portions of the factual record relating to the dermal contact provisions.[85]

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals respecting the dermal contact sections should be affirmed.[86]

Respectfully submitted,

CHARLES F. LETTOW
JOHN C. MURPHY, JR.
1250 Connecticut Ave., N.W.
Washington, D.C. 20036

Attorneys for
The Rubber Manufacturers
Association, Inc., *et al.*

Of Counsel:

CLEARY, GOTTLIEB, STEEN
& HAMILTON
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036

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[85] If, however, this Court does choose to take on that task and duplicate it, the result should remain the same.

[86] If this Court should determine not to affirm the court of appeals' judgment respecting the dermal contact sections, the case should be remanded to the court of appeals among other things for consideration of the feasibility of the requirements of these sections, an issue which the court below did not reach. *See supra*, at 16.